

DECLARATION OF CONFORMITY

MEDICAL DEVICE DIRECTIVE 93/42/EEC
PERSONAL PROTECTIVE EQUIPMENT DIRECTIVE 89/686/EEC

Legal Manufacturer:

Semperit Investments Asia Pte Ltd
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Authorized representative in the EC:

Semperit Technische Produkte Gesellschaft m.b.H
Modecenterstraße 22
1030 Vienna, Austria

This certificate is valid for the following product:

Non-sterile examination and protective glove for single use

Classification: class I according to MD Directive; category I according to PPE Directive

sempercure vinyl powder free (100 pcs)

Sizes	X-Small	Small	Medium	Large	X-Large
Art. No.	825781031	825781033	825781035	825781037	825781039
Alt. Art. No.	3000001970	3000001971	3000001972	3000001973	3000001974

We hereby declare under sole responsibility that the CE marked product described above conforms to the essential requirements (Annex I) of the directive for medical devices 93/42/EEC.

The conformity assessment is based on Annex VII. Classification according to rule 5, Annex IX.

Applied standards: EN 455-1:2000, EN 455-2:2009+A2:2013 & EN 455-2:2015, EN 455-3:2006 & EN 455-3:2015, EN 455-4:2009, ISO 10993-1:2013, EN ISO 15223-1:2017, EN 1041:2013, EN ISO 14971:2013, DIN ISO 2859-1:2014, , EN ISO 13485:2016

We hereby certify that the CE marked product described above conforms with the applicable provisions of the directive for personal protective equipment 89/686/EEC.

Applied standards: EN 420:2003+A1:2009



Andreas Wöss
Director



Released by: Johann Glantschnig
Regulatory Affairs Manager Sempermed

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